Section 5: 510k) Summary

The Summary of Safety and Effectiveness on the Radial Artery Compression Tourniquet reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant:	Lepu Medical Technology (Beijing) Co., Ltd. No. 37 Chaoqian Road Changping District, Beijing 102200 P.R. China SEP 2 7 2011
Telephone:	+86-10-80120641
Date:	June 27, 2011
Name:	Radial Artery Compression Tourniquet
Common Name:	Vascular Compression Device
Classification Name:	Vascular Clamp
Classification:	870.4550
Product Code:	DXC
Predicate:	TR Band®, Terumo Corporation, K070423 and RadAR™ Vascular Compression Devices, Advanced Vascular Dynamics Division, K092503 with market clearance dates of March 28, 2007 and November 19, 2009 respectively.
Description:	The Radial Artery Compression Tourniquet devices consist of a plastic belt with an adjustable fastener on each end, two compression balloons, tubing and a unilateral valve. The plastic belt has a support plate over the two compression balloons to assure that the balloons and belt conform to the contour of the wrist and are made of clear plastic which allows the physician to view the access site during the haemostasis process. The inflation device introduces air through the unilateral valve filling two compression balloons (large and small) at the same time. The top small balloon is layered and internally connected to the bottom large balloon. The result of the balloon inflation is the haemostasis of the puncture site within the patient's wrist.
Intended Use	The Radial Artery Compression Tourniquet Device is a compression device to assist haemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, haemodialysis, and in patients on anticoagulation therapy.
Contraindications	• Patients hypersensitive to the materials of compression device. • Patients with infection or other serious skin diseases at the site of puncture. • Patients with an abnormal Allen test or radial pulse, or insufficient dual arterial supply. • Not intended for femoral artery compression.

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Warning	• Patients should not be left unattended while the Radial Artery Compression Tourniquet is in use. • Ensure correct alignment of the Radial Artery Compression Tourniquet prior to use. • Do not inject air into any port other than the air injection port of this device. • Do not leave Radial Artery Compression Tourniquet on for inappropriately long periods of time as tissue damage may occur. • Arterial pulse distal to the compression site should be monitored to ensure the artery is not completely occluded as arterial damage and/or thrombosis could occur.
Caution	• Ensure correct placement of Radial Artery Compression Tourniquet. • Federal (USA) law restricts this device to sale by or on the order of a physician. • The product is intended for single use only. • Do not reuse or re-sterilize. • Do not use if package opened or damaged. • Over inflation of balloon > 20 ml as balloon damage could occur compromising the performance of the Radial Artery Compression Tourniquet. • The diameter of the wrist at the site of puncture is too large or too small, which exceeds the allowable range of compression device.
Substantial Equivalency Information	The information provided in this submission, comparing intended use, principle of operation and overall technological characteristics, the Radial Artery Compression Tourniquet Devices is substantially equivalent to existing legally marketed devices and the operational differences between the predicate device RadAR^{tm} Vascular Compression Devices and the Radial Artery Compression Tourniquet Devices does not present a significant effect in the therapeutic outcome.
Tests Conducted	Biocompatibility: The Radial Artery Compression Tourniquet was assessed against the standard ISO 10993 Biological Evaluation of Medical Devices – Part 10 for Irritation and Sensitization and Part 5 Tests for Cytotoxicity, has been shown to meet the acceptance criteria, and did not raises additional safety and effectiveness concerns. Performance: A side-by-side comparison of the predicate TR Band®, Terumo Corporation, K070423 performance of the balloon's maintenance of internal pressure was performed with the Lepu's device. The balloon profile performance characteristics of both devices are very similar when factoring the balloon size and volume inflation difference and do not impose any additional safety or performance issues.
Technological Characteristics	The device features of the Lepu LPY20 models Radial Artery Compression Tourniquet and the predicate devices are very similar. All three products have an adjustable strap and apply pressure to the puncture site in the patient's arm. There are some design variations, but these do not affect the substantial equivalence of the Lepu LPY20 Radial Artery Compression Tourniquet Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

SEP 27 2011

Lepu Medical Technology (Beijing) Co., Ltd.
c/o Mr. Arthur S. Goddard
FDA Regulatory and Quality Systems Consultant
1531 Felton Road
South Euclid, OH 44121-2722

Re: K111837
Trade/Device Name: Radial Artery Compression Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: June 27, 2011
Received: June 29, 2011

Dear Mr. Goddard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K111837

Device Name: **Radial Artery Compression Tourniquet**

Indications for Use:

The Radial Artery Compression Tourniquet is a compression device to assist haemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use _X___
(Per 21 CFR 801.109)

Over-The-Counter Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111837